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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	IR 6493-02	3786

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,127	ZICKER ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39, 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's request for continued examination under 37 CFR 1.114 and the amendment received May 11, 2005.

Claims 1-38, 40-43 are cancelled. No new claims are added. Claims 39, 44-47 are currently pending.

The previous claim rejection under 35 USC 102(e) over Hamilton 6,335,361 set forth in paragraphs 4-5 of the office action mailed Nov. 3, 2003 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth in paragraph 2 of the office action mailed Jan. 11, 2005 have been considered but are moot in view of the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 39, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper WO 00/44375 ('375) in view of Hamilton 6,335,361 (both references already of record).

Harper teaches a method for overcoming the problem of oxidative stress in a companion animal such as a dog or cat by increasing the plasma Vitamin E levels in the cat or dog. Specifically, a diet containing Vitamin C and Vitamin E are fed to senior (6.5-12.5 years of age) dogs. Harper discloses that such a vitamin "cocktail" will prevent or treat a disorder (aging), which has a component of oxidative stress. Additionally, Harper teaches a method of feeding vitamin E separately to the companion animal in order to increase the Vitamin E levels in the plasma thereby overcoming the problem of oxidative stress. Please see the abstract, page 1, lines 18-21; page 13, line 12; page 16, lines 20-23; Example 19, pages 47-48.

Harper does not teach adding antioxidants such as alpha lipoic acid or l-carnitine or mixtures thereof. Yet, the Examiner refers to Hamilton, which discloses a method of treating cognition disorders associated with aging. Specifically, the method involves administering an effective amount of a combination of the antioxidants carnitine and α-lipoic acid. A preferred form of carnitine is acetyl-L- carnitine and R-α-lipoic acid. Moreover, Hamilton teaches that the combination of antioxidants may be added to pet food for administration to animals such as cats, dogs, horses, birds and fish. The

combination of antioxidants serves to inhibit age-related memory loss and provide improved memory in older subjects. The combination of antioxidants contributes to the improvement of mental acuity. Finally, Hamilton discloses that additional nutrients such as vitamin E or C should be included as they are particularly important in older subjects. Please see col. 6, lines 44-60; col. 7, lines 14- 17; col. 8, lines 8-13; col. 10, lines 9-21.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Harper to specifically administer to the aged dog or cat Vitamin E, C in combination with l-carnitine and α-lipoic acid because one of ordinary skill in the art would reasonably expect the combination of these anti-oxidant compounds to inhibit oxidative stress associated with aging. Moreover, since Hamilton discloses a method of improving memory in older pets as well as a method of treating cognitive disorders (e.g. age-related memory loss) by administering carnitine and α-lipoic acid, one of ordinary skill in the art would reasonably expect the combination of anti-oxidants not only to inhibit oxidative stress associated with aging but also to counteract age-related memory loss and improve mental acuity in the aged cats and dogs taught of Harper. Finally, even Hamilton suggests that additional administration of vitamin E or C would serve to enhance the treatment process by teaching that these anti-oxidants are particularly important in older subjects and should be included in the diet.

Concerning the claimed dosage amounts, since Hamilton and Harper establish that effective amounts, i.e. dosage amounts, are necessary to the treatment of disorders/symptoms associated with aging and oxidative stress, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts of Hamilton and Harper such that the dosage amounts of the carnitine, vitamin E, vitamin C and alpha-lipoic acid are effective to inhibit oxidative stress or symptoms associated with aging in animals, thereby improving mental acuity and inhibiting age-related memory loss.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 39, 44-47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30 of copending Application No. 09/978,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and co-pending application '132 claim a method of inhibiting the loss of learning ability of a companion pet, wherein the method comprises feeding the pet a mixture of antioxidants containing vitamin E, vitamin C, alpha-lipoic acid or L-carnitine.

The difference between the claims of the instant application and the claim of copending application '132 is that claim 30 of '132 specifically treats a cat or dog of 1 to 6 years. However, the scope of the claims of the instant application and claim 30 of copending application '132 overlap because the claims of the instant application encompass treatment of cats and dogs and because the antioxidants or mixture of antioxidant being fed to the pet are substantially identical.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 39, 44-47 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
June 13, 2005

Cybille Delacroix-Muirheid
Patent Examiner Group 1600